



May 6, 2014

Health Advisory

**Important Information Regarding Glucose Test Strips
and Coagulation Test Strips**

The North Dakota Department of Health, Division of Health Facilities has been made aware of concerns related to two separate laboratory products:

- Shasta Technologies GenStrip Blood Glucose Test Strips
- Alere INRatio[®] 2 PT/INR Professional Test Strips

The Shasta Technologies GenStrip Blood Glucose Test Strips may report false results. During a recent inspection of Shasta Technologies LLC, the FDA found extensive violations of federal regulations intended to assure the quality of products in the manufacturing of GenStrip Test Strips. GenStrip Blood Glucose Test Strips, sold by Shasta Technologies LLC, are “third-party” blood glucose monitoring test strips. Shasta’s GenStrips are advertised for use with the LifeScan OneTouch family of glucose meters (e.g. Ultra, Ultra 2 and Ultra Mini). The FDA recommends using alternative glucose test strips that are designed for use with the OneTouch family of glucose meters. The affected test strips have been manufactured and distributed since March 2013 and are available through online retailers and retail pharmacies. The strips may be packaged in green and white packaging with the GenStrip name on top. More information can be found at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm395180.htm>.

Alere is initiating a voluntary Urgent Product recall of the Alere INRatio[®] 2 PT/INR Professional Test Strips. This voluntary Urgent Product recall only concerns the professional test strips (PN 99008G2). This is as a result of several complaints of patients who had a therapeutic or near-therapeutic INR with the Alere INRatio2 PT/INR Professional Test Strip, but a significantly higher INR (outside of therapeutic range) when performed by a central laboratory. For more information about the Alere INRatio2 PT/INR Professional Test Strip voluntary Urgent Product recall, please review the [customer letter sent out on April 16, 2014](#) and the [press release issued on May 6, 2014](#).

Thank you for your attention to this information. If you have any questions, please feel free to contact our office at 701.328.2352.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, and hospital public information officers.